

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, <i>ex rel.</i>	:	
DILBAGH SINGH, M.D.,	:	Civil Action No. 04-186E
PAUL KIRSCH, M.D.,	:	
V. RAO NADELLA, M.D., and	:	
MARTIN JACOBS, M.D.,	:	The Honorable Judge Cohill
 Relators,		
 v.	:	
 BRADFORD REGIONAL		
MEDICAL CENTER,	:	
V & S MEDICAL ASSOCIATES, LLC,	:	
PETER VACCARO, M.D.,	:	
KAMRAN SALEH, M.D.,	:	(Filed Electronically)
and DOES I through XX,	:	
 Defendants.		

**V&S MEDICAL ASSOCIATES, LLC, PETER VACCARO, M.D. AND KAMRAN
SALEH, M.D.'S MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION FOR SUMMARY JUDGMENT**

Defendants V&S Medical Associates, LLC (“V&S”), Peter Vaccaro, M.D. (“Vaccaro”), and Kamran Saleh, M.D., (“Saleh”) (collectively referred to as the “V&S Defendants”), by their counsel, file the following Memorandum of Law in Support of Their Motion for Summary Judgment:

I. SUMMARY OF ARGUMENT

The present qui tam action was commenced by Dilbagh Singh, M.D., Paul Kirsch, M.D., V. Rao Nadella, M.D., and Martin Jacobs, M.D. (hereafter collectively referred to as the “Relators”) under the federal False Claims Act (the “FCA”), 31 U.S.C. §§ 3729-3732. The Relators’ allegations rest entirely on the assertion that a sublease of medical equipment between

Bradford Regional Medical Center (“BRMC”) and V&S (the “Sublease”), as well as related arrangements, violate the Anti-kickback Statute, 42 U.S.C. § 1320a-7b(b) (the “AKS”) and/or the Physician Self-Referral Act, 42 U.S.C. § 1395nn (the “Stark Law”).

However, contrary to the assertions made by the Relators in this case, the Sublease and related arrangements do not violate the AKS and/or the Stark Law, because either the Stark Law does not apply to the Sublease and related arrangements in this case, or they fall within the express regulatory exceptions and/or safe harbors set forth in the Stark Law and the AKS. Accordingly, the V&S Defendants have not violated the FCA and are entitled to summary judgment in their favor.

Furthermore, even without a finding that the Stark Law does not apply to the Sublease and related arrangements, or that the Sublease and related arrangements fit within the exceptions or safe harbors of the Stark Law or the AKS, the V&S Defendants are still entitled to summary judgment in their favor, given that the Relators have not and cannot establish any FCA violation on the part of the V&S Defendants. The V&S Defendants have not made any false or fraudulent claims for payment to the United States Government and have not used or made a false record or statement to the Government, nor did they have any reason to believe that their actions would or could cause the filing of a false claim or use of a false record or statement. In addition, the evidence in this case has established that the V&S Defendants did not possess the required scienter for any FCA violation, and the Relators have failed to prove to the contrary. Therefore, the V&S Defendants are entitled to summary judgment on all claims asserted against them in the Complaint.

II. STATEMENT OF FACTS AND PROCEDURAL HISTORY

A. Factual Background¹

Drs. Vaccaro and Saleh are the sole and equal owners of a two-physician medical practice in the small town of Bradford, Pennsylvania. (Stmt. of Facts 2). Drs. Vaccaro and Saleh specialize in the practice of internal medicine and are members of the medical staff of BRMC. (Stmt. of Facts 3). Vaccaro and Saleh were previously employed by BRMC, but in 2000, they purchased their practice from BRMC and created V&S. (Stmt. of Facts 4). The transaction included a payment by Vaccaro and Saleh of \$300,000 to BRMC to release the doctors from two year non-compete agreements they had in their employment agreements with BRMC. *Id.*

In 2001, approximately one year after purchasing their practice, Vaccaro and Saleh decided to expand their practice by leasing a nuclear camera and performing related diagnostic services for their patients in their office. (Stmt. of Facts 5). However, shortly after they were committed to their nuclear camera lease, they were informed by BRMC that by operating a nuclear camera in their office, the doctors would likely be in violation of BRMC's recently approved new Policy On Physicians With Competing Financial Interests ("the Policy"). (Stmt. of Facts 6). The Policy and its related procedures identified certain competing interests that would result in a physician being ineligible for medical staff appointment and clinical privileges at BRMC. *Id.*

The V&S Defendants, who simply wanted to operate a nuclear camera in their office, were faced with limited choices as a result of BRMC's new Policy. (Stmt. of Facts 7). They could (i) continue to operate the nuclear camera and allow BRMC to withdraw their privileges (a

¹ The V&S Defendants incorporate herein by reference their Concise Statement of Material Facts in Support of Their Motion For Summary Judgment (hereinafter "Stmt. of Facts").

significant consequence in a small, one hospital town like Bradford, Pennsylvania); (ii) stop using their nuclear camera for which they had a contractual commitment, forego the associated revenue, and suffer the related economic consequences; (iii) engage in costly litigation with BRMC over its ability to deny their privileges with a potential negative outcome given the existing legal climate and state of the law at the time; or (iv) seek some other resolution with BRMC. *Id.*

The V&S Defendants and their counsel spent almost two years intensely negotiating with BRMC over the appropriateness and legality of enforcing the Policy against Drs. Vaccaro and Saleh, at a significant cost for all parties, and ultimately sought a compromise to resolve their dispute prior to what could have been costly, disruptive, drawn-out litigation. (Stmt. of Facts 8). One of the solutions proposed by BRMC during these negotiations was an arrangement whereby nuclear cardiology imaging studies would be provided “under arrangement” by an entity that would be owned by physicians on the BRMC medical staff to BRMC patients (“the Under Arrangements Venture”). (Stmt. of Facts 9). The V&S Defendants agreed to pursue this option, provided (i) that an acceptable financial arrangement could be reached and (ii) that the final arrangement received the appropriate regulatory approval in the form of an Advisory Opinion from the HHS Office of the Inspector General. *Id.*

However, given the amount of time required to explore and implement the Under Arrangements Venture, the parties negotiated a temporary and/or alternate resolution to their two-year dispute while the Under Arrangements Venture negotiations continued. (Stmt. of Facts 10). In particular, in 2003, BRMC and V&S negotiated and ultimately entered into a sublease (the “Sublease”), under which V&S leased its nuclear camera to BRMC for a period of five years. *Id.* The Sublease is due to expire on September 30, 2008. *Id.*

Under the Sublease, BRMC pays a monthly amount to V&S which represents V&S' pass through costs for leasing the nuclear camera equipment, as well as an additional payment for V&S' agreement (i) not to own or operate competing nuclear cardiology imaging equipment within 30 miles of BRMC; and (ii) not to provide other outpatient diagnostic imaging services within 30 miles of BRMC while the Under Arrangements Venture is in development, or if the Under Arrangements Venture is not implemented, to give BRMC a right of first refusal for any other competing diagnostic imaging services. (Stmt. of Facts 12).

The Sublease expressly provides that if an Under Arrangements Venture is successfully implemented, then the Sublease automatically terminates. (Stmt. of Facts 13). Ultimately, though, BRMC has been unable to generate sufficient support for the Under Arrangements Venture and it has not gone forward. *Id.*

Under the terms of the Sublease, the V&S Defendants are not required to refer any patients to BRMC. (Stmt. of Facts 14). Furthermore, neither payment for the non-compete, nor the pass through costs vary based on the volume or value of any services referred to BRMC by Vaccaro and Saleh. *Id.* Vaccaro and Saleh have continued to make all of their referral decisions in the same manner that they did before they leased any nuclear camera equipment, on a case-by-case basis, based upon convenience, patient preference, and what is in the best interests of the patients. (Stmt. of Facts 15).

The payment amount in the Sublease is essentially a straight pass through of V&S' cost for leasing nuclear camera equipment, plus a negotiated amount for the non-compete component of the Sublease. (Stmt. of Facts 16). V&S valued the non-compete component of the Sublease based upon the value of what they gave up under the Sublease. (Stmt. of Facts 17). This included: (i) the convenience and financial benefit of operating a nuclear camera in their office

and the ability to operate any other nuclear camera within 30 miles of BRMC; and (ii) the ability to engage in future ventures such as CT, MRI, or other diagnostic imaging services, without giving BRMC the right of first refusal. *Id.*

BRMC also independently valued the non-compete portions of the Sublease and arrived at its own value based upon its estimate of a fair price for V&S to get out of the nuclear camera business, which proved to be generally consistent with the amount proposed by the V&S Defendants. (Stmt. of Facts 18). Furthermore, BRMC had an independent valuation of the entire Sublease performed by an independent valuation expert, prior to execution, in order to ensure that it was fair market value, and BRMC communicated this fact to the V&S Defendants. (Stmt. of Facts 19).

As the Sublease was being finalized, BRMC decided to invoke a negotiated provision under the Sublease that allowed it to upgrade the nuclear camera equipment from the GE camera used by the V&S Defendants to a new Phillips nuclear camera. (Stmt. of Facts 20). The upgrade resulted in a slightly higher pass through cost paid by BRMC for the new equipment. *Id.* However, the amount paid for the non-compete remained the same. *Id.*

During an unexpected delay in upgrading the nuclear camera, the GE camera was not relocated to BRMC. (Stmt. of Facts 21). Instead, BRMC entered into a separate agreement for temporary use of the space and services of V&S by BRMC (the “Space and Services Agreement”). *Id.* The Space and Services Agreement was memorialized in the form of a written proposal and invoice from V&S, and the invoice was approved and executed by BRMC’s Chief Financial Officer. *Id.* The Space and Services Agreement, which was in effect for only several months and terminated in June of 2004, called for BRMC to pay V&S (i) \$2,500 per month for the space where the GE camera was located in V&S’ offices, (ii) pass through charges for

performance of nuclear cardiology tests, and (iii) a billing fee equal to 10% of the amounts collected for nuclear cardiology services while tests were being performed at V&S on behalf of BRMC. *Id.*

B. Procedural History

The Relators filed their Complaint in this action under seal on July 2, 2004. (Dkt. No. 1). The United States investigated the matter and declined to intervene on May 11, 2005. (Dkt. No. 6). The Complaint was unsealed and served on the Defendants on June 23, 2005. (Dkt. Nos. 9-12). The Defendants filed a Joint Motion to Dismiss, which was denied by the Court on September 13, 2006. (Dkt. No. 31). Defendants filed their Answers on October 13, 2006. (Dkt. Nos. 35 and 36). All of the parties engaged in discovery, including the production of documents and responses to interrogatories. Depositions were taken of (i) the corporate representatives of BRMC pursuant to Federal Rule of Civil Procedure 30(b)(6), (ii) BRMC's Chief Executive Officer George Leonhardt as an individual, (iii) Drs. Saleh and Vaccaro, (iv) attorneys Alan Steinberg and Edward Kabala, who represented BRMC and V&S, respectively, during the Sublease negotiations, (v) all four Relators, and (vi) the expert witnesses designated by both sides. The V&S Defendants' Motion for Summary Judgment and supporting documentation is now being filed in accordance with the Court's Final Case Management Order (Dkt. No. 109).

III. ARGUMENT

A. Summary Judgment Standard

Under Federal Rule of Civil Procedure 56(c), summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," demonstrate "no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). In addition, Rule 56(c)

mandates the entry of summary judgment, after adequate time for discovery, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the movant's initial burden can be met simply by "pointing out to the district court that there is an absence of evidence to support the non-moving party's case." *Celotex*, 477 U.S. at 325.

After the moving party has met its initial burden, the non-moving party bears the burden of demonstrating that there are disputes of material fact that should proceed to trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). An issue is genuine only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party, and a factual dispute is material only if it might affect the outcome of the suit under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). To meet this burden, the non-moving party must point to specific, affirmative evidence in the record and not simply rely on unsupported allegations, mere suspicions, or denials in the pleadings. *Celotex*, 477 U.S. at 324-25; *Williams v. Borough of W. Chester*, 891 F.2d 458, 460 (3d Cir. 1989). In the present case, the Relators cannot show that there is any genuine issue for trial for the reasons set forth below.

B. The Sublease And Other Financial Relationships Between BRMC And V&S Do Not Violate The Stark Law Or The Anti-kickback Statute.

The V&S Defendants fully incorporate by reference hereto the arguments and positions asserted by co-Defendant BRMC in Sections II(B)(1) and II(B)(2) of Bradford Regional Medical Center's Memorandum in Support of Motion for Summary Judgment. As set forth in further detail in BRMC's Memorandum, the Stark Law does not apply to the relationships between

BRMC and V&S, or to the referrals made by Vaccaro or Saleh to BRMC, which have been attacked by the Relators in this case.² However, even if the Stark Law did apply, the Sublease and other arrangements at issue in this litigation would be permitted by regulatory exception to the Stark Law. In addition, the Sublease and other arrangements at issue in this litigation also squarely fit within the safe harbors permitted by the AKS.

Without any violations of either the Stark Law or the AKS, there are no violations of the FCA in this case. Accordingly, the V&S Defendants are entitled to summary judgment on all of the Relators' claims against them.

C. The Relators Have Failed To Establish A Violation Of The False Claims Act By The V&S Defendants.

Even assuming *arguendo* that the Court cannot determine on summary judgment that the Stark Law does not apply to the Sublease and related arrangements, or that the Sublease and related arrangements fit within the exceptions or safe harbors of the Stark Law and the AKS, the Relators have nonetheless still failed to establish a violation of the FCA by the V&S Defendants. The Relators must ultimately prove that there was a violation of the FCA by the V&S Defendants in order to prevail against them, since there is no private right of action under the AKS. *West Allis Memorial Hospital v. Bowen*, 852 F.2d 251, 254-55 (7th Cir. 1988). Similarly, the Relators lack standing to pursue a claim against the V&S Defendants for a violation of the Stark Law. *United States, ex rel. Repko v. Guthrie Clinic*, 557 F.Supp.2d 522, 529 (M.D.Pa.

² As described more fully in BRMC's Memorandum, the Stark Law only applies if there is a direct or indirect financial relationship between **individual referring physicians** and the provider of designated health services (in this case, BRMC). 42 U.S.C. § 1395nn (a)(1). Relators have introduced no evidence to support such a direct relationship. Moreover, in order to establish an indirect compensation relationship between BRMC and Vaccaro or Saleh, the Relators would need to show, among other criteria, that compensation received by Vaccaro or Saleh from V&S varied with or took into account the volume or value of referrals they made to BRMC. 42 C.F.R. § 411.354(c)(2). Relators have introduced no such evidence, and in fact the compensation paid by V&S to the individual physicians was divided equally and did not vary with or take into account any referrals made by the physicians. (Stmt. of Facts 2, 27).

2008). Accordingly, all of the claims asserted against the V&S Defendants in the Complaint are under the FCA, and not the AKS or the Stark Law. (*See* Complaint pp. 23-25).

The FCA, in relevant part, imposes civil money penalties upon the following:

(a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; ...or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government.

31 U.S.C. § 3729(a). Three elements must exist for FCA liability: "(1) the defendant submitted a claim to the government; (2) which was false; and (3) which the defendant knew was false."

United States, ex rel. Pogue v. Diabetes Treatment Centers of America, 2008 WL 2791687 (D.D.C.) at *4, citing, *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F.Supp.2d 25, 57 (D.D.C. 2007).

1. The V&S Defendants Did Not Present A False Or Fraudulent Claim Or Make Or Use A False Record Or Statement.

There are absolutely no allegations in this case that the V&S Defendants submitted any claims to the Government for reimbursement for services that were not actually provided by them. (Stmt. of Facts 23). In addition, there are no allegations that the V&S Defendants submitted any claims to the Government for reimbursement for services they provided that were not medically necessary. (Stmt. of Facts 24). In fact, the Relators have all admitted that they have no knowledge of and no evidence of any false claims submitted by the V&S Defendants to the Government. (Stmt. of Facts 22).

As noted above, the Relators case rests entirely on the contention that the Sublease and related arrangements violate the AKS and/or the Stark Law. Based on this contention, the

Relators assert that BRMC (not the V&S Defendants) submitted false claims to Medicare, Medicaid and CHAMPUS/Tricare for services performed on patients allegedly referred by Drs. Vaccaro and Saleh, allegedly in violation of the FCA. (Complaint ¶ 4). As evidenced by their Complaint, the Relators' claims are primarily based on a "false certification" theory, which contends that because the claims for reimbursement and/or cost reports submitted by BRMC allegedly contain certifications that BRMC is in compliance with the law, and because the Sublease allegedly violated the law, all of the claims for payment for services provided by BRMC to patients covered by these federal programs who were referred by Drs. Vaccaro and Saleh, are allegedly false. (Complaint ¶ 6).

However, there is absolutely no evidence in this case of any alleged false or fraudulent claims submitted by the V&S Defendants, or any alleged false record or statement made by the V&S Defendants to the Government, such as a cost report or certification of compliance. The claims at issue in the case are the claims submitted by BRMC resulting from alleged referrals by the V&S Defendants to BRMC.

The Relators assert FCA violations arising out of the certifications of compliance contained in hospital cost reports submitted to the Government by BRMC. However, the V&S Defendants had no involvement in the preparation, review or submittal of any cost reports submitted to the Government by BRMC. (Stmt. of Facts 25). Prior to this litigation, the V&S Defendants were not aware of the cost reports filed by BRMC and other hospitals, or any certifications which may be included with the hospital cost reports. *Id.* This contention is corroborated by the Relators themselves, who are all other physicians in the Bradford region, and who admit to also being unaware of the hospital cost reports and accompanying certifications, prepared and submitted by BRMC, prior to this litigation. *Id.*

In light of the above, the only way that the V&S Defendants could have committed a FCA violation would be if they had knowingly caused a false or fraudulent claim for payment to be made, knowingly caused a false record or statement to be submitted, or knowingly conspired to defraud the Government. However, none of these occurred either. As set forth below, the evidence in the case has clearly established that the V&S Defendants lacked the required scienter for any FCA violation.

2. The V&S Defendants Lacked The Required Scienter For A False Claims Act Violation.

Any violation of the FCA requires a finding of scienter, and therefore, for a qui tam action to survive summary judgment, a relator must produce sufficient evidence to support an inference of knowing fraud by the defendant. *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477, n. 21 (9th Cir. 1996). The FCA defines “knowing” as including a defendant’s “actual knowledge,” “deliberate ignorance,” or “reckless disregard” of the truth or falsity of information in a claim submitted to the Government. *United States, ex rel. Hefner v. Hackensack University Medical Center*, 495 F.3d 103, 109 (3d. Cir. 2007); *see also* 31 U.S.C. § 3729(b); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 241 (3d Cir. 2004). Significantly, “(t)he requisite intent is the knowing presentation of what is known to be false, as opposed to innocent mistake or mere negligence.” *Hagood*, 81 F.3d at 1478; *see also Hefner*, 495 F.3d at 109 (noting Congress’ specifically expressed intent that the FCA not punish honest mistakes or mere negligence).

In the present case, there is not one scintilla of evidence of intentional or even reckless fraud on the part of the V&S Defendants.³ To the contrary, the evidence overwhelmingly

³ At the summary judgment stage, a relator is held to a higher burden than at the motion to dismiss stage and must establish actual evidence that a defendant possessed the requisite knowledge for a violation, as opposed to simply

establishes that the V&S Defendants merely sought a legal compromise to a long, costly dispute with BRMC over its Policy Against Competing Financial Interests. (Stmt. of Facts 8). As set forth in more detail in Section III(B) above, and in Sections II(B)(1) and II(B)(2) of BRMC's Memorandum, there was, at an absolute minimum, a good faith basis for the V&S Defendants to reasonably believe that this had been accomplished. The V&S Defendants never agreed to refer any patients to BRMC after the Sublease was executed. (Stmt. of Facts 14). Furthermore, nothing in the Sublease requires the V&S Defendants to refer any patients to BRMC, and the amounts in no way vary based upon the value or number of any referrals. *Id.* Saleh and Vaccaro have continued to make all of their referral decisions in the same manner that they did before the Sublease, and before leasing a nuclear camera, on a case-by-case basis, based entirely upon convenience, patient preference, and what is in the best interests of the patients. (Stmt. of Facts 15).

In his deposition, counsel for the V&S Defendants, Ed Kabala, testified regarding the discussions that occurred between the parties and their legal counsel at a meeting in early 2003: "the original concept was to discuss how the parties could back off from the precipice that they—the deadlock, the fight that they were involved in [over the Policy], and whether there were legal ways to resolve the issue." (Stmt. of Facts 8). Mr. Kabala then provided further testimony regarding a March, 8, 2003 meeting between the parties and their counsel, when the sublease negotiations first began in earnest:

(a)t this stage the concept was to have Drs. Vaccaro and Saleh eventually join in to something called an under arrangements model. We were discussing whether the parties could wait for the under arrangements model to be implemented or whether there was a way that we could legally develop some methodology for the hospital to take over the nuclear camera and the nuclear camera business at an

making conclusory allegations. See *Pogue*, 2008 WL 2791687 at *16 (awarding summary judgment due to the lack of evidence to support that the defendant possessed the requisite knowledge for a violation).

earlier stage because it would take some time for the under arrangements model to be implemented.

(Stmt. of Facts 9, 10).

BRMC, the V&S Defendants, and their legal counsel, spent almost two years negotiating and discussing the dispute between the parties over BRMC's Policy, and exploring various options before eventually arriving at a potential sublease, and even then, the parties spent an additional seven months working out the details of the Sublease, including ensuring that it was fair market value. (Stmt. of Facts 11). During that seven month period, the V&S Defendants provided BRMC with data regarding V&S' operation of a nuclear camera in its office, to support the non-compete numbers proposed by V&S. *Id.* In addition, BRMC had a third-party valuation expert review the proposed transaction to ensure it was fair market value. (Stmt. of Facts 19). *See Hefner*, 495 F.3d at 110 (finding lack of scienter for a FCA claim, particularly given the hiring of a consultant to improve compliance issues).

The V&S Defendants understood that BRMC did not want V&S to continue to perform nuclear camera testing in their office. (Stmt. of Facts 10). They knew that BRMC also wanted to find a way to resolve the parties' ongoing dispute. (Stmt. of Facts 8). Furthermore, during this time period, BRMC also had a need for a second nuclear camera. (Stmt. of Facts 10). Accordingly, as a logical solution, the parties pursued and ultimately agreed upon a sublease of equipment with a non-compete provision.

It remains undisputed that the Stark Law and the AKS both expressly permit rental arrangements for equipment between hospitals and physicians' practices. *See* 42 C.F.R. § 411.357(b) and 42 C.F.R. § 1001.952(c), respectively. It is further undisputed that the Stark Law and the AKS do not prohibit non-compete agreements. In fact, Federal Law clearly recognizes a distinction between a requirement to refer and a non-compete provision, such as in

the present case. In the Preamble to the January 4, 2001 Phase I Stark Regulations, the HCFA, now the Center for Medicare & Medicaid Services, expressly addressed the issue of restrictive covenants when it stated: “(a) requirement to refer to a specific provider is different from an agreement not to establish a competing business.” 66 Fed. Reg 879 (Jan. 4, 2001).⁴

As noted above, the evidence supports that there was a clear intent by the V&S Defendants for the Sublease and related arrangements to comply with the Stark Law and the AKS, as well as a belief by the V&S Defendants that they did in fact comply.⁵ (Stmt. of Facts 29). In keeping with this intention, the V&S Defendants believed that the Sublease and related arrangements were fair market value, separate and apart from any consideration of referrals. (Stmt. of Facts 30).

Mr. Kabala provided further testimony regarding the negotiations between BRMC and the V&S Defendants over the Sublease.

- Q. And did you relate to the hospital that it was – that whatever arrangement was agreed upon would have to compensate the physicians for the loss of the business opportunity or the loss of the profit? Is that what you were –
- A. They were giving up some profit of \$240,000 initially and then more later, so my proposal was that they compensate the doctors for the camera, the cost of the camera and basically for a noncompete. The form, whether we did it as a sublease or a sublease and a noncompete or whatever, all those things were talked about, and it basically got down to one document.

⁴ Accordingly, the mere fact that Drs. Vaccaro and Saleh referred patients to BRMC after the Sublease and related arrangements were entered into does not create knowledge on their part of any fraud or inevitable false claims. Prior to the Sublease, and prior to obtaining a nuclear camera in their office, Vaccaro and Saleh referred many patients to BRMC for nuclear camera testing. (Stmt. of Facts 15). After the Sublease, in keeping with the permissible federal regulations, the V&S Defendants knew they were free to refer patients where they wanted, provided they did not violate the non-compete provisions of the Sublease, and they continued to make case-by-case decisions, based upon convenience, patient preference, and what was in the patient’s best interests. *Id.*

⁵ By contrast, while a few recent decisions in the Third Circuit *have* found sufficient intent to support an FCA violation in a party that did not itself submit false claims or reports to the Government, these cases have featured a clear overt wrongful intent on the part of the non-submitting party. *See Schmidt*, 386 F.3d at 244 (a non-submitting orthopedic implant maker created a marketing program for its products that it knew to be in violation of the AKS and the Stark Act); *United States v. Torkelsen*, 2007 WL 4245736, *7 (E.D.Pa.) (two individual defendant “created and pursued a complex scheme that they knew would require [a third defendant] to submit false certifications to the government”).

Q. Well, was it the hospital that requested the noncompete, or was it the doctors that proposed the noncompete?

A. I don't know that – I think probably that I proposed the noncompete. Again, we had been looking for an appropriate methodology that was satisfactory to the government, that was satisfactory to the lawyers and satisfactory to the clients, and that was one that was basically in use in many, many transactions that were ongoing in the '90s and early 2000s and still today.

*** *** ***

Q. And did the hospital, during the course of those discussions, did the hospital relate to you a reason or justification for their position that they were willing to pay something, but not as much as you were looking for?

A. Well, the hospital wanted to – if the hospital wanted to take it over, then they are to be certain that what they were paying was fair market value. They thought the original number wasn't, or even if it was, they weren't ready to pay it. So they were going to consider what they thought was fair market value for taking over this business and for the noncompete.

Q. When you say "fair market value for taking over the business," at this point the sale of the business was off the table. Is that true? Is that correct?

A. Well, there was no purchase of the business.

Q. Okay.

A. But the doctors would give up the business pursuant to the noncompete. So the hospital would be taking over the tech, the camera, moving it to the hospital, and integrating it into their department initially and ultimately into the under arrangements model, if that took off and went anywhere.

(Stmt. of Facts 17, 18).

The V&S Defendants valued the non-compete component of the Sublease based upon the value of what they were giving up under the Sublease. (Stmt. of Facts 17). BRMC testified that it also independently valued the non-compete portions of the Sublease and arrived at its own value based upon its estimate of a fair price for V&S to get out of the nuclear camera business.

(Stmt. of Facts 18). This is consistent with what was communicated to the V&S Defendants during the negotiations of the Sublease. *Id.* Furthermore, BRMC also communicated to the V&S Defendants that it had an independent valuation of the entire Sublease performed by a valuation expert prior to execution in order to ensure that it was fair market value. (Stmt. of Facts 19).

Significantly, as part of this litigation, the Defendants also jointly had a second nationally recognized valuation expert review the Sublease and related arrangements, and this valuation expert provided yet another opinion that they are all fair market value. (Stmt. of Facts 32). The Relators, on the other hand, have never had a valuation performed on the Sublease and related arrangements and have not and cannot offer any expert opinions that the Sublease and related arrangements are not, in fact, fair market value. (Stmt. of Facts 31).

The Relators attempt to ignore the clear intent and significant efforts of the parties to comply with the law, by arguing that the Sublease and other arrangements “otherwise reflect” the value of referrals because BRMC allegedly took into account the expected value it would get from referrals when it calculated the non-compete amounts paid to V&S under the Sublease. (Plaintiff’s Response to Defendant Bradford Regional Medical Center’s Motion to Quash at p. 5). This position, which is inconsistent with what was expressed to the V&S Defendants, is denied. However, even if, solely for the sake of argument, this were true, the V&S Defendants never took into account the value of any referrals when they calculated the amounts in the Sublease and related arrangements, and there is no evidence to the contrary. (Stmt. of Facts 17). Furthermore, there is no evidence that the V&S Defendants were aware that BRMC allegedly took into account the value of any referrals during the negotiations of the Sublease, or that BRMC ever communicated that they were doing so. (Stmt. of Facts 18). When asked if BRMC

shared information on referral rates or business volumes as part of the Sublease negotiations, counsel for the V&S Defendants, Ed Kabala, testified: “The only information we ever received from the hospital was information generally at some point on the under arrangements model. There was never any question of referrals.” *Id.*

The Relators’ expert suggests that various documents such as the written valuation prepared by BRMC’s third-party valuation expert, Charles Day, and internal BRMC documentation prepared for the BRMC Board of Directors, support the Relators’ contention that referrals were taken into consideration by BRMC as part of the Sublease negotiations. However, even if this were the case, which is denied, the V&S Defendants never saw these documents prior to the litigation. (Stmt. of Facts 26). There is simply no evidence supporting that the V&S Defendants possessed the required scienter for a FCA violation.

Accordingly, for all the reasons set forth above, the Relators have failed to meet their burden of establishing that the V&S Defendants knowingly made or caused to be made a false or fraudulent claim to the Government, or made or caused to be used a false record or statement. Therefore, summary judgment should be granted in favor of the V&S Defendants on Counts One through Three of the Complaint.

In addition, the Relators have also failed to establish evidence of a conspiracy involving the V&S Defendants under the FCA. The essence of a conspiracy under the FCA is “an agreement between two or more persons to commit a fraud.” *United States, ex rel. Atkinson, v. Pennsylvania Shipbuilding Co.*, 2004 WL 1686958, *4 (E.D.Pa.), aff’d 473 F.3d 506 (3d Cir. 2007). Put another way, a plaintiff “must present evidence that would enable a reasonable juror to conclude that [the defendants] shared a “conspiratorial objective.” *Id.* Furthermore, because “[g]eneral principles of civil conspiracy apply to FCA conspiracy claims,” a plaintiff must show

“(1) a combination of two or more persons acting with a common purpose to do an unlawful act or to do a lawful act by unlawful means or for an unlawful purpose; (2) an overt act done in pursuance of the common purpose; and (3) actual legal damage” *Id.*

The Relators’ own expert, a former hospital administrator, acknowledges that there is nothing inherently unlawful about either a sublease for medical equipment, or a non-compete agreement between a hospital and a physicians’ practice. (Stmt. of Facts 28). Therefore, for this arrangement to be unlawful, it would require knowledge by the V&S Defendants that an inevitable consequence of the Sublease and related arrangements would be fraud perpetrated on the Government. *See United States, ex rel. Atkinson, v. Pennsylvania Shipbuilding Co.*, 2000 WL 1207162, *11 (E.D.Pa.). As set forth above, the evidence does not support the existence of any knowledge on the part of the V&S Defendants that rises to the level of scienter for a conspiracy claim under the FCA, and therefore summary judgment should also be granted in favor of the V&S Defendants on Count Four of the Complaint.

The FCA is not intended to punish individuals who do not intend to violate any law and carefully attempt to structure a legal and proper arrangement. The Relators want to place this entire transaction under a microscope and, with the benefit of hindsight, say that the parties “could have done this” or “should have done that.” This is not, however, the type of situation to which the FCA is intended to apply.

Drs. Vaccaro and Saleh are two physicians simply trying to provide quality care for their patients and operate a profitable medical practice. They have now been subjected to years of litigation and related costs, solely as a result of their having attempted to resolve another long, costly legal dispute, in a fashion they reasonably believed to be in compliance with the law. Accordingly, the V&S Defendants have not violated the False Claims Act.

IV. CONCLUSION

For the foregoing reasons, Defendants V&S Medical Associates, LLC, Peter Vaccaro, M.D., and Kamran Saleh, M.D. respectfully request that their Motion for Summary Judgment be granted and that summary judgment be entered in their favor and against Plaintiffs on all claims in the Complaint.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of September, 2008, a true and correct copy of the foregoing Memorandum of Law in Support of Its Motion for Summary Judgment was served via the Court's ECF transmission facilities upon the following counsel of record:

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